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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,864	07/11/2006	Patrick Dawson Bailey	BJS-620-527	7738

23117 7590 11/24/2009

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EXAMINER	
NIEBAUER, RONALD T	
ART UNIT	**PAPER NUMBER**
1654	

MAIL DATE	DELIVERY MODE
11/24/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/585,864	BAILEY, PATRICK DAWSON	
	Examiner	Art Unit	
	RONALD T. NIEBAUER	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-25,27-32,34-36,40 and 41* is/are pending in the application.

4a) Of the above claim(s) *6,8-24,34-36 and 41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-5,7,25,27-32 and 40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 July 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

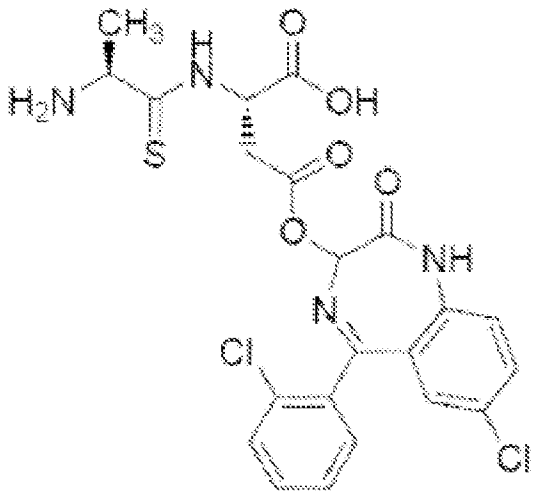
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/27/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election of Group 2 in the reply filed on 11/5/08 and the species of conjugate of:



in the reply filed on 7/20/09 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The elected species was not found in the prior art. It is noted that no claim reads solely on the elected species. As such, whether or not the species is supported by the original specification has not been considered. In accord with section 803.02 of the MPEP the search was extended to another species. As discussed below, art was found that reads on the instant Markush-type claim. As such, the examination has been extended to the extent necessary to determine patentability of the Markush type claim but has not been extended unnecessarily to cover all nonelected species.

Although applicants have amended claims 34-35, claims 34-35 remain a separate group. Claim 28 and group 2 is drawn to drug conjugates. Claims 34-35 are drawn to detectors to detect drug conjugates. Claim 36 also remains a separate group.

It is noted that claims 8-9 and dependent claims are unclear. While claim 28 is drawn to a drug conjugate, claims 8-9 refer to a compound which is a part of the conjugate. However, the formulas of claims 8-9 do not appear to include a drug. It is unclear where the drug would be conjugated to the formulas as recited in claims 8-9. As currently interpreted the art cited below does not read on claims 8-9 and dependent claims, thus claims 8-9 and dependent claims are withdrawn.

Claims 34-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/5/08.

Claims 6,8-24,41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 7/20/09.

Claims 1,26,33,37-39 have been cancelled.

Claims 2-5,7,25,27-32,40 are under consideration.

Information Disclosure Statement

The information disclosure statement filed 11/27/06 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. 37 CFR 1.98(b)5 states " Each publication listed in an information disclosure statement must be identified by publisher, author (if any), title, relevant

pages of the publication, date, and place of publication." However, the title has not been provided for any of the NPL documents.

It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Specification

The disclosure is objected to because of the following informalities:

The specification page 4 line 7 lists the pages of the publication as 3864-3864. The actual pages of the publication are 3861-3864.

Appropriate correction is required.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.

(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
(f) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

In the instant case, the section 'brief description of the drawings' (see page 24 of the specification) has not been included (see MPEP section 608.01(f)).

Appropriate correction is required.

Claim Objections

Claim 40 is objected to because of the following informalities:

Claim 40 recite 'an antibiotics'. It would seem that the phrase 'an antibiotic' is appropriate in the context of claim 40. Claim 40 recites CNS. However, the abbreviation has not been spelled out in the claims.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-5,7,25,27-32,40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 28 is drawn to a drug conjugate and further states 'and a functional group for attachment to a drug'. Since the claim is drawn to a drug conjugate, it is unclear if the 'drug' is the drug that is part of the drug conjugate or if it is in reference to a different drug. As such, it is unclear how many drugs are attached. In other words, since the claim is to a drug conjugate a compound is attached to a drug. However, the claims recite 'functional group for attachment' which makes it unclear if the functional group is attached or if the group is capable of being attached. A functional group that is attached to a drug is structurally distinct from a functional group that is not attached to a drug. Dependent claims 2-5,7,25,27,29-32,40 do not clarify the meaning of claim 28 and are thus included in the rejection. Claim 2 states that the compound is adapted to or capable of carrying or transporting a drug. It is unclear if the 'drug' referred to in claim 2 is the drug of the drug conjugate or if it is a 2nd drug. A compound that is capable of transporting a drug is structurally distinct from a compound that is conjugated to a drug.

Claim 7 recites 'thio group is attached at, or towards, an N-terminal thereof'. The meaning of an attachment 'towards' a certain location is unclear. The term 'towards' is a relative term which renders the claim indefinite. The term 'towards' is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 30 states that the attachment of the drug occurs at residue 1 or 2. However, the identity of residue 1 or 2 is unclear. There is no direction provided as to how to identify residue 1 or 2. It is noted that the compound can be a derivative or analogue. There is no direction provided as to how to identify residues of derivatives or analogues.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-5,7,25,27-32,40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc.,

> that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

> "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus …") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163. The MPEP does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163. While all of the factors have been considered, a sufficient amount for a *prima facie* case are discussed below.

Further, to provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include: a) the scope of the invention; b) actual reduction to practice; c) disclosure of drawings or structural chemical formulas; d) relevant identifying characteristics including complete structure, partial structure, physical and/or chemical properties, and structure/function correlation; e) method of making the claimed compounds; f) level of skill and knowledge in the art; and g) predictability in the art.

(1) Level of skill and knowledge in the art/predictability in the art:

The level of skill in the art is high. There is unpredictability in predicting functional effects of replacements. It is not within the skill of the art to predict any and all replacements that would result in compounds that are adapted to carry or transport a drug as recited in claim 28 or that are adapted to be transported by a PepT1 protein or a PepT2 protein as recited in claim 3

(2) Scope of the invention/Partial structure/disclosure of drawings:

In the instant case, the claims are drawn to drug conjugates. The specification broadly defines drug to include an active compound or molecule (page 2 lines 24-25). Although claim 40 recites classes of drugs none of the dependent claims provide specific partial structure for the drugs. Claim 28 states that the compound linked to the drug can be a thiopeptide or derivative or analogue. First, it is noted that thiopeptide has been broadly defined (page 6 lines 1-4) such that a 'thio functional' group be present and such that (page 5 line 30) a peptide bond is not required. Further, the specification does not provide a specific definition of derivatives and analogues but suggests that they can include a range of structural variations (page 11 lines 13-19). Further, the dependent claims do not limit the thiopeptide or analogue or derivative to a significant core structure. For example, claims 4-5 recite analogues and derivatives. Thus the scope of the analogues and derivatives and also the drug conjugates is nearly limitless. As such, the genus is large. Claim 7 merely recites a thio group and claim 29 merely recites a bond. One would not recognize a single functional group or a bond as a significant partial structure of a drug conjugate.

Although unclear (see 112 2nd) the claims have been interpreted such that there is a single drug conjugated to a compound or drug carrier. Although unclear (see 112 2nd) the claims have been interpreted such that 'towards' can be any where on the molecule. Although unclear (see 112 2nd) the claims have been interpreted such that residue 1 or 2 can be any residue.

It is noted that figures 1 and 6 provide examples of conjugates. However, such conjugates are not representative of the scope of the instant claims. While figures 1 and 6 appear to have a backbone core of H2N-C-CS-NH-CO the instant claims are not limited to such structure. In the

instant case, the drug merely needs to be an active molecule (page 2 lines 24-25) and the compound can be an analogue or derivative.

There is substantial variability in the genus. Since there are a substantial variety of compounds possible within the genus, the examples do not constitute a representative number of species and do not sufficiently describe the genus claimed (see Gostelli above).

(3) Physical and/or chemical properties and (4) Functional characteristics:

Claim 28 states that the compound is adapted to carry or transport a drug. Claim 3 states that he compound is adapted to be transported by a PepT1 protein or a PepT2 protein. Further claim 28 refers to a 'drug conjugate' wherein the drug can be an active molecule. However, there is no specific disclosed correlation between structure and function. It is unclear what structural elements are required for the recited function. There are no common attributes or characteristics that identify compounds to be transported by a PepT1 or PepT2 protein. As such, one of skill in the art would not recognize a core structure, common attributes, or features of such compounds. One of skill in the art would not recognize drug conjugates outside of those specifically identified such as those in the Figures. There is no teaching in the specification regarding what part of the structure can be varied while retaining the ability to act as a drug or active molecule. In particular, no common core sequence is taught. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus and that there is a lack of the knowledge in the art regarding which amino acids can vary to maintain the function and thus that the applicant was not in possession of the claimed genus.

(5) Method of making the claimed invention/actual reduction to practice:

The specification (specifically page 25) describes the making conjugate compounds. Figures 1,6 shows specific conjugates. However, such conjugates are not representative of the instant genus nor do the conjugates provide a specific correlation between structure and function such that one could identify any and all drug conjugates where the compound is adapted to be transported by a PepT1 protein or a PepT2 protein.

As stated supra, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that claim(s) 2-5,7,25,27-32,40 is/are broad and generic, with respect to all possible compounds encompassed by the claims. The possible structural variations are many. Although the claims may recite some functional characteristics, the claims lack written description because there is no specific disclosure of a correlation between function and structure of the compounds beyond those compounds specifically disclosed in the examples in the specification. Moreover, the specification lacks sufficient variety of species to reflect this variance in the genus. While having written description of compounds identified in the specification tables and/or examples, the specification does not provide sufficient descriptive support for the myriad of compounds embraced by the claims.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention

achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

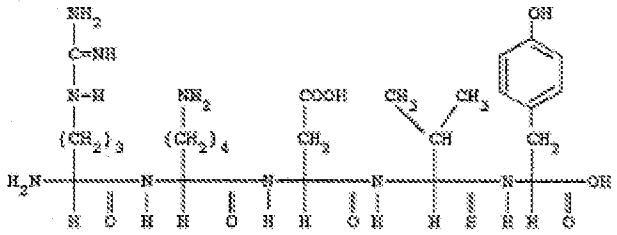
Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2-5,7,25,27-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Brillon et al (WO 91/01976 as cited in IDS 11/27/06).

Brillon teach using thioamide bonds in peptides (abstract). Brillon teach that the incorporation of thioamide linkages increases resistance to enzymatic digestion (page 23 lines 13-16). Brillon teach that 4-thiothymopentin (formula VII page 22, also example 4 page 45)



(VII)

has higher biological activity than the unmodified polypeptide.

In relation to the instant claims, 4-thiothymopentin (formula VII page 22) is a thiopeptide (It is noted that the instant specification (page 6 lines 1-4) defines thiopeptide such that a 'thio functional' group be present and such that (page 5 line 30) a peptide bond is not required) which comprises a C-terminal carboxylic acid. Further, since the CS group is connected to the rest of the peptide it is has a functional group for attachment as recited in claim 28. The instant specification defines drug (page 2 lines 24-25) to include any active compound or molecule. Since Brillon teach 4-thiothymopentin has an immunomodulatory activity (page 45 line 12), 4-thiothymopentin comprises a drug. Thus, 4-thiothymopentin meets the limitations of claims 27-28. Since 4-thiothymopentin contains NHCO the attachment is via an amide as recited in claim 29. Since there is one amino acid after the CS (i.e. on the C-terminal side) the attachment is interpreted as being at the 2nd residue from the C-terminus thus meeting the limitations of claim 30.

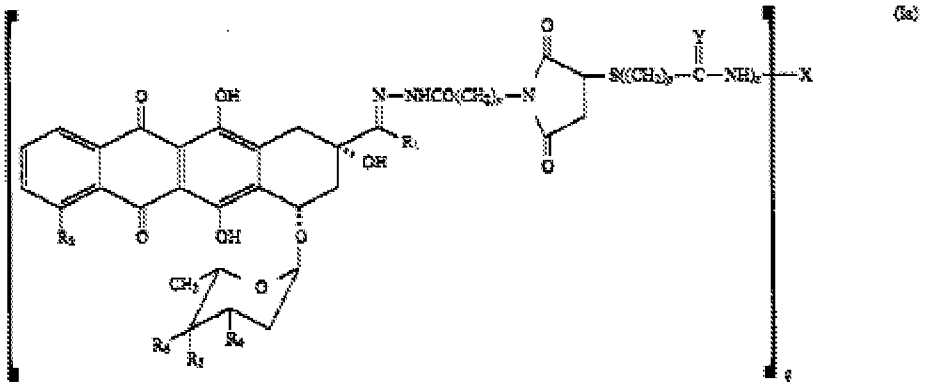
Since the structure of Brillon meet the structural limitations the structure would have the properties as recited in claim 31. Further, it is noted that as claimed, the release or detachment as recited in claim 31 can be via any means. Brillon teach the use of 4-thiothymopentin in the form of pharmaceutical formulations (page 45) thus meeting the limitations of claim 32.

Since the structure of Brillon meet the structural limitations the structure would have the properties as recited in claims 2-3 absence evidence to the contrary. 4-thiothymopentin comprises at least two amino acids as recited in claims 4-5. The thio group in 4-thiothymopentin is towards the N-terminal end since it is not the C-terminal amino acid thus the limitations of claim 7 are met. A functional group, for example CH(CH3)2 of the structure of 4-thiothymopentin would act as a protecting group as recited in claim 25.

Although unclear (see 112 2nd) the claims have been interpreted such that there is a single drug conjugated to a compound or drug carrier. Although unclear (see 112 2nd) the claims have been interpreted such that 'towards' can be any where on the molecule. Although unclear (see 112 2nd) the claims have been interpreted such that residue 1 or 2 can be any residue.

Claims 2-5,7,25,27-32,40 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilner et al (US 5,606,017).

Wilner teach thioether conjugates (title, abstract). Wilner specifically teach conjugates in which a drug moiety (D) is linked to a thioether moiety (A-S-) which is linked to a ligand (X) (abstract). Wilner teach that the preferred drugs are anti-cancer drugs (column 4 lines 66-67 through column 5 line 1). Wilner teach adriamycin as the most preferred drug (column 9 lines 66-67). In formula Ia (columns 25-26)



Wilner teach adriamycin conjugated to a thioether ligand moiety. Wilner teach the conjugates in the form of pharmaceutical formulations (column 25 lines 64-66).

In relation to the instant claims, adriamycin as taught by Wilner (column 25 line 58 for example) meets the limitations of the drug as recited in claim 28, specifically an anticancer drug (see column 4 lines 66-67 of Wilner) as recited in claim 40. Wilner teach the conjugates as thioether conjugates (abstract) and specifically shows a sulfur atom that connects to the drug moiety (formula Ia column 25-26). As such, Wilner teach a compound comprising s thiopeptide derivative or analogue thereof as recited in claims 27-28. Since a thioether contains a sulfur atom it is a derivative or analogue of a thiopeptide. It is noted that the instant specification (page 6 lines 1-4) defines thiopeptide such that a 'thio functional' group be present and such that (page 5 line 30) a peptide bond is not required. Since the conjugate of Wilner comprise a sulfur the limitations of claim 7 are met. It is noted that claim 28 refers to a C-terminal carboxylic acid group, however such group is only required when the compound is a thiopeptide. Since Wilner teach a thiopeptide derivative the C-terminal carboxylic acid group is not required. It is noted that claim 28 recites that the compound is adapted to carry or transport the drug. The compound of Wilner meet the structural limitations and further Wilner teach the conjugates to deliver the drug (column 1 line 13 and column 3 line 41 for example). Since the conjugate of Wilner contains NHCO (Formula Ia columns 25-26) the attachment is via an amide as recited in claim 29. Further the attachment of the drug is at a residue of the conjugate which although unclear (see discussion below) is taken to be residue 1 as recited in claim 30. Since the conjugate of Wilner meet the structural limitations the conjugate would have the properties as recited in claim 31. Further, it is noted that as claimed, the release or detachment as recited in claim 31 can be via any means. Wilner teach the conjugates in the form of pharmaceutical formulations (column 25 lines 64-66) thus meeting the limitations of claim 32. Since the conjugate of Wilner meet the

structural limitations the conjugate would have the properties as recited in claims 2-3 absence evidence to the contrary. Claims 4-5 refer to derivatives and analogues. In accord with section 2111 of the MPEP the conjugates of Wilner meet the limitations since the analogues can be analogous in any fashion. Since Wilner teach antibodies as the ligand (see Figure 1 for example) the antibodies would function to protect the drug thus the limitations of claim 25 is met.

Although unclear (see 112 2nd) the claims have been interpreted such that there is a single drug conjugated to a compound or drug carrier. Although unclear (see 112 2nd) the claims have been interpreted such that 'towards' can be any where on the molecule. Although unclear (see 112 2nd) the claims have been interpreted such that residue 1 or 2 can be any residue.

Related Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Huber et al (US 5,662,911). Huber teach benzodiazepine conjugates (see formula Ia column 2). It is noted that formula Ia shows a NCH3 group (column 2 line 39) where lorazepam has a NH group.

Hubbell et al (US 20030220245). Hubbell teach (page 40 example 12, especially section 0406) thiol peptide drug conjugates.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD T. NIEBAUER whose telephone number is (571)270-3059. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, alt. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Anish Gupta/
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